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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,861	02/11/2000	CARLO RICCARDI	RICCARDI=1	7791

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EXAMINER
EPPS, JANET L

ART UNIT	PAPER NUMBER
1635	20

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/403,861	Applicant(s) RICCARDI, CARLO	
	Examiner Janet L. Epps	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. Applicant is reminded that in order to avoid an abandonment of this application, the drawings must be corrected in accordance with the instructions set forth in Paper No. 16, mailed on 8-08-2001.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments regarding the rejection of claims 11-12 and 26 under 35 USC § 112, first paragraph, and as applied to newly filed claims 41-48, are considered moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 41-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims read on GILR protein comprising the amino acid sequence according to SEQ ID NO: 2, and a derivative thereof, wherein said GILR protein and derivative are capable of inhibiting apoptosis in cells or stimulating lymphocyte activity. Additionally, the instant

claims read on a GILR protein encoded by SEQ ID NO: 1, or encoded by a cDNA sequences that hybridizes to a sequence "derived" from SEQ ID NO:1.

Applicant's specification does not sufficiently describe a clear nexus relationship between the amino acid structure of the GILR protein and the claimed functional limitations wherein the GILR protein is "capable of inhibiting apoptosis and stimulating lymphocyte activity." The specification as filed defines the term "derivatives" as encompassing "derivatives which may be prepared from the functional groups which occur as side chains on the residues or the N- or C-terminal groups, by means known in the art, and are included in the invention. Derivatives may have chemical moieties such as carbohydrate or phosphate residues, provided such a fraction has the same or higher biological activity as GILR proteins." Furthermore, the specification states that "derivatives may be prepared by standard modifications of the side groups of one or more amino acid residues of the GILR protein, its analogs or fragments, or by conjugation of the GILR protein, its analogs or fragments, to another molecule e.g. an antibody, enzyme, receptor, etc." (Specification page 33, lines 1-18).

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state that:

> "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

In view of applicant's definition of the term "derivatives," the GILR proteins of instant invention encompass a broad genus of molecules including modified analogs or fragments of the GILR proteins of the present invention that are not adequately described by Applicant's disclosure. One of skill in the art would not be able to immediately envision the structures of the full scope of compounds encompassed by the claimed genus. Therefore applicants were not in possession of the full scope of the claimed GILR protein derivatives according to the present invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 43-44 and 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Shibanuma et al. and Jay et al.

The instant claims read on a GILR derivatives comprising at least part of the amino acid sequence according to SEQ ID NO: 2, or 5, and encoding at least one active human GILR protein. It is also noted that applicants do not clearly define the intended meaning of the term "have at least part of" with regards to SEQ ID NO: 1, 2, or 5. Additionally, the term "pharmaceutical" recited in claim 26 is not given any patentable weight for prior art purposes, claim 26 is interpreted as reading on a composition comprising at least one GILR protein or its biologically active derivatives or mixtures thereof.

The prior art clearly discloses that members of the GILR family of leucine zipper proteins share a high degree of sequence homology between members of the protein family. Shibanuma et al. and Jay et al. disclose proteins sharing at least part of the DNA sequence of SEQ ID NO: 1, and at least part of the amino acid sequence according to SEQ ID NO: 2 and further encodes a leucine zipper family related protein.

Shibanuma et al. disclose the mouse TSC-22 leucine zipper containing protein. This is a protein of 143 amino acids, and comprises 89 identical residues of the GILR protein according to SEQ ID NO: 2 of the instant application. Therefore Shibanuma et al. disclose a protein comprising at least part of a protein according to SEQ ID NO: 2, according to the instant application.

Jay et al. disclose the human TS-22 leucine zipper containing protein. The TS-22 protein comprises a sequence that is 70% identical to the polypeptide according to SEQ ID NO: 2 of the instant application. Therefore the polypeptide of Jay et al. clearly comprises at least a part of the GILR proteins of the instant application.

Therefore, Shibanuma et al. and Jay et al. teach each and every aspect of the instant application thereby anticipating applicant's claimed invention.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps, Ph.D.
Examiner
Art Unit 1635

JLE
May 17, 2002

SEAN McGARRY
PRIMARY EXAMINER
1635